

**K100151 APEX HIP SYSTEM BIPOLAR HEAD, MODEL H3-822XX  
(OD 38 TO 43MM), H3-828XX (OD44 TO 60MM)**May 28, 2010  
129 days to decisionK100151 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k100151/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Jan 19, 2010
Decision date	May 28, 2010
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Omnlife Science</b>
Location	Raynham, MA, US
Contact	Robert Zoletti
510(k) history	6 submissions · 6 cleared · 2008-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100151/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 17, 2026